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*C. R. Bard, Inc. and*  
*Bard Peripheral Vascular, Inc.*

**IN THE UNITED STATES DISTRICT COURT**  
**FOR THE DISTRICT OF ARIZONA**

IN RE: Bard IVC Filters Products Liability     MDL NO. 15-02641-PHX-DGC  
Litigation

This Document Relates to:

MYRA EDWARDS,

Plaintiff,

CASE NO. CV-15-2090-PHX-DGC

v.

C. R. BARD, INC., a New Jersey  
Corporation; and BARD PERIPHERAL  
VASCULAR INC., an Arizona  
Corporation,

**DEFENDANTS C. R. BARD, INC. AND  
BARD PERIPHERAL VASCULAR,  
INC.'S ANSWER AND DEFENSES TO  
PLAINTIFF'S COMPLAINT AND  
DEMAND FOR TRIAL BY JURY**

Defendants.

Defendants C. R. Bard, Inc. ("Bard") and Bard Peripheral Vascular, Inc. ("BPV")  
(collectively "Defendants"), through undersigned counsel, hereby file their answer and  
defenses to Plaintiff's Complaint (the "Complaint") as follows:



any damages whatsoever. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, jurisdiction appears to be proper in the United States District Court for the Western District of Virginia.

8. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, venue appears to be proper in the United States District Court for the Western District of Virginia.

### **FACTUAL ALLEGATIONS**

9. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny the remaining allegations contained in Paragraph 9 of Plaintiff's Complaint

10. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Meridian® were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Meridian®. Defendants deny the remaining allegations contained in Paragraph 10 of Plaintiff's Complaint.

11. Defendants deny the allegations contained in Paragraph 11 of Plaintiff's Complaint.

12. Defendants deny the allegations contained in Paragraph 12 of Plaintiff's Complaint.

13. Defendants deny the allegations contained in Paragraph 13 of Plaintiff's Complaint.

14. Defendants deny the allegations contained in Paragraph 14 of Plaintiff's Complaint.

1           15. Defendants deny the allegations contained in Paragraph 15 of Plaintiff's  
2 Complaint.

3           16. Defendants lack knowledge or information sufficient to form a belief as to the  
4 truth of the allegation regarding the time frame when inferior vena cava filters were first  
5 introduced on the market or the identity of manufacturers of inferior vena cava filters.  
6 Defendants deny any remaining allegations of Paragraph 16 of Plaintiff's Complaint.

7           17. Defendants admit that inferior vena cava filters are intended to prevent injury or  
8 death resulting from venous thrombosis and pulmonary embolism. Defendants further admit  
9 that inferior vena cava filters may be designed for permanent placement, temporary  
10 placement, or both. Defendants deny any remaining allegations of Paragraph 17 of Plaintiff's  
11 Complaint.

12           18. Defendants admit that the inferior vena cava is a large vein that receives blood  
13 from the lower regions of the body and delivers it to the right atrium of the heart. Defendants  
14 further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to  
15 human health, including sometimes death. Defendants deny any remaining allegations of  
16 Paragraph 18 of Plaintiff's Complaint.

17           19. Defendants admit that certain people are at an increased risk for the  
18 development of deep vein thrombosis and pulmonary embolus, but lack sufficient information  
19 to form a belief as to the truth of the allegations as stated regarding the various risk factors  
20 which may predispose an individual to deep vein thrombosis or pulmonary emboli and thus  
21 deny them. Defendants deny any remaining allegations of Paragraph 19 of Plaintiff's  
22 Complaint.

23           20. Defendants admit that patients at a high risk for developing deep vein  
24 thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy,  
25 including but not limited to the medications listed in Paragraph 20 of Plaintiff's Complaint.  
26 Defendants further admit that inferior vena cava filters may also be used to treat patients who  
27 are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants  
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1 lack knowledge or information sufficient to form a belief as to the truth of any remaining  
2 allegations contained in Paragraph 20 of Plaintiff's Complaint and, on that basis, deny them.

3       21. Defendants lack knowledge or information or information sufficient to form a  
4 belief as to the truth of the allegation regarding the time frame when inferior vena cava filters  
5 were first introduced on the market. Defendants also lack knowledge or information sufficient  
6 to form a belief as to the truth of the allegation regarding the time frame when optional or  
7 retrievable filters came to be marketed or the other allegations regarding optional or  
8 retrievable filters marketed by other manufacturers. Defendants admit that the Recovery®,  
9 G2®, G2® Express, Eclipse®, and Meridian® Filters were cleared by the FDA for optional  
10 use as retrievable inferior vena cava filters. Defendants deny any remaining allegations  
11 contained in Paragraph 21 of the Complaint.

12       22. Defendants admit that the Recovery® Filter was cleared by the FDA for  
13 permanent placement on November 27, 2002, pursuant to an application submitted under  
14 Section 510(k) of the Food, Drug and Cosmetic Act of 2005. The allegations pertaining to the  
15 requirements of Section 510(k) contained in Footnote 1 are conclusions of law to which no  
16 answer is required. Defendants deny any remaining allegations contained in Paragraph 22 of  
17 Plaintiff's Complaint, including all sub-parts thereof and including any allegations contained  
18 in Footnote 1.

19       23. Defendants admit that the Recovery® Filter was cleared by the FDA for  
20 retrievable placement on July 25, 2003, pursuant to an application submitted under  
21 Section 510(k) of the Food, Drug and Cosmetic Act of 2005. Defendants deny any remaining  
22 allegations contained in Paragraph 23 of Plaintiff's Complaint.

23       24. Defendants deny the allegations contained in Paragraph 24 of Plaintiff's  
24 Complaint.

25       25. Defendants admit that the Recovery® Filter consists of twelve, shape memory  
26 Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the  
27 twelve wires form two levels of filtration for emboli: the legs provide the lower level of  
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1 filtration, and the arms provide the upper level of filtration. Defendants deny any remaining  
2 allegations contained in Paragraph 25 of Plaintiff's Complaint.

3       26. Defendants admit that a nickel-titanium alloy named Nitinol is used in the  
4 manufacture of the Recovery® Filter and further admits that Nitinol contains shape memory.  
5 However, to the extent Paragraph 26 purports to cast liability either directly or indirectly  
6 upon Defendants, said Paragraph is expressly denied.

7       27. Defendants admit that the Recovery® Filter was designed to be inserted  
8 endovascularly. Defendants further admit that the Recovery® Filter is designed to be  
9 delivered via an introducer sheath, which is included in the delivery system for the device.  
10 Defendants are without knowledge or information sufficient to form a belief as to the truth of  
11 the allegations contained in Paragraph 27 of Plaintiff's Complaint regarding the typical  
12 practices of physicians, including physician methods for determining successful implantation  
13 of the Recovery® Filter, and, on that basis, such allegations are denied. Defendants deny any  
14 remaining allegations of Paragraph 27 of Plaintiff's Complaint.

15       28. Defendants deny the allegations contained in Paragraph 28 of Plaintiff's  
16 Complaint, including any allegations contained in Footnote 2.

17       29. Defendants deny the allegations contained in Paragraph 29 of Plaintiff's  
18 Complaint.

19       30. Defendants deny the allegations contained in Paragraph 30 of Plaintiff's  
20 Complaint.

21       31. Defendants deny the allegations contained in Paragraph 31 of Plaintiff's  
22 Complaint.

23       32. Defendants admit that there are various well-documented complications that  
24 may occur as the result of the fracture and/or migration of any inferior vena cava filter. Bard  
25 states that there are incidents related to the occurrence of known complications associated  
26 with every manufacturer of inferior vena cava filters. By way of further response, Bard states  
27 that information available in the public domain, including the FDA MAUDE database, is not  
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1 a comprehensive analysis of all instances of such complications. Defendants deny the  
2 remaining allegations of Paragraph 32 of Plaintiff's Complaint, and all sub-parts thereof.

3 33. Defendants deny the allegations contained in Paragraph 33 of Plaintiff's  
4 Complaint.

5 34. Defendants deny the allegations contained in Paragraph 34 of Plaintiff's  
6 Complaint.

7 35. Defendants deny the allegations contained in Paragraph 35 of Plaintiff's  
8 Complaint.

9 36. Defendants admit that there are various well-documented complications that  
10 may occur as a result of the fracture, migration, tilt, and/or perforation of any inferior vena  
11 cava filter. Defendants further admit that it is well documented that many instances of filter  
12 fracture, migration, tilt, and/or perforation result in no complications whatsoever but, rather,  
13 are completely asymptomatic. By way of further response, Bard states that there are incidents  
14 related to the occurrence of known complications associated with every manufacturer of  
15 inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 36 of  
16 Plaintiff's Complaint, including all sub-parts thereof.

17 37. Defendants deny the allegations contained in Paragraph 37 of Plaintiff's  
18 Complaint.

19 38. Defendants deny the allegations contained in Paragraph 38 of Plaintiff's  
20 Complaint.

21 39. Defendants admit that, as part of their continuing efforts to constantly evaluate  
22 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are  
23 continually striving to improve the life-saving performance of those devices. The G2®,  
24 G2®X, Eclipse™, and Meridian® filters were developed in furtherance of those efforts.  
25 Defendants deny the remaining allegations contained in Paragraph 39 of Plaintiff's  
26 Complaint.

1           40. Defendants admit that, as part of their continuing efforts to constantly evaluate  
2 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are  
3 continually striving to improve the life-saving performance of those devices. The G2® Filter  
4 was developed in furtherance of those efforts. Defendants deny the remaining allegations  
5 contained in Paragraph 40 of Plaintiff's Complaint.

6           41. Defendants admit the G2® Filter System was cleared by the United States Food  
7 and Drug Administration pursuant to an application submitted under Section 510(k) of the  
8 Food, Drug and Cosmetic Act in 2005. Defendants admit that the G2® Filter was originally  
9 cleared by the FDA for permanent use. Defendants further admit that the G2® Filter was  
10 subsequently cleared by the FDA for optional use as a retrievable inferior vena cava filter.  
11 Defendants deny any remaining allegations contained in Paragraph 41 of Plaintiff's  
12 Complaint, including any allegations contained in Footnote 3.

13           42. Defendants deny the allegations contained in Paragraph 42 of Plaintiff's  
14 Complaint.

15           43. Defendants deny the allegations contained in Paragraph 43 of Plaintiff's  
16 Complaint.

17           44. Defendants deny the allegations contained in Paragraph 44 of Plaintiff's  
18 Complaint.

19           45. Defendants deny the allegations contained in Paragraph 45 of Plaintiff's  
20 Complaint.

21           46. Defendants admit that there are various well-documented complications that  
22 may occur as a result of the fracture, migration, tilt, and/or perforation of any inferior vena  
23 cava filter. Defendants further admit that it is well documented that many instances of filter  
24 fracture, migration, tilt, and/or perforation result in no complications whatsoever but, rather,  
25 are completely asymptomatic. By way of further response, Bard states that there are incidents  
26 related to the occurrence of known complications associated with every manufacturer of  
27  
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1 inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 46 of  
2 Plaintiff's Complaint, including all sub-parts thereof.

3 47. Defendants admit that there are various well-documented complications that  
4 may occur as the result of the fracture of any inferior vena cava filter. Bard states that there  
5 are incidents related to the occurrence of known complications associated with every  
6 manufacturer of inferior vena cava filters. By way of further response, Bard states that  
7 information available in the public domain, including the FDA MAUDE database, is not a  
8 comprehensive analysis of all instances of such complications. Defendants deny the  
9 remaining allegations of Paragraph 47 of Plaintiff's Complaint.

10 48. Defendants deny the allegations contained in Paragraph 48 of Plaintiff's  
11 Complaint.

12 49. Defendants admit the G2® Express Filter System was cleared by the United  
13 States Food and Drug Administration pursuant to an application submitted under  
14 Section 510(k) of the Food, Drug and Cosmetic Act in 2008. Defendants deny any remaining  
15 allegations contained in Paragraph 49 of Plaintiff's Complaint.

16 50. Defendants admit the G2®X Filter System was cleared by the United States  
17 Food and Drug Administration pursuant to an application submitted under Section 510(k) of  
18 the Food, Drug and Cosmetic Act in 2008. Defendants deny any remaining allegations  
19 contained in Paragraph 50 of Plaintiff's Complaint.

20 51. Defendants deny the allegations contained in Paragraph 51 of Plaintiff's  
21 Complaint.

22 52. Defendants deny the allegations contained in Paragraph 52 of Plaintiff's  
23 Complaint.

24 53. Defendants deny the allegations contained in Paragraph 53 of Plaintiff's  
25 Complaint.

26 54. Defendants deny the allegations contained in Paragraph 54 of Plaintiff's  
27 Complaint.

1           55. Defendants deny the allegations contained in Paragraph 55 of Plaintiff's  
2 Complaint.

3           56. Defendants deny the allegations contained in Paragraph 56 of Plaintiff's  
4 Complaint.

5           57. Defendants deny the allegations contained in Paragraph 57 of Plaintiff's  
6 Complaint.

7           58. Defendants admit the Meridian® Filter System was cleared by the United States  
8 Food and Drug Administration pursuant to an application submitted under Section 510(k) of  
9 the Food, Drug and Cosmetic Act in 2011. Defendants deny any remaining allegations  
10 contained in Paragraph 58 of Plaintiff's Complaint.

11           59. Defendants admit that, as part of their continuing efforts to constantly evaluate  
12 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are  
13 continually striving to improve the life-saving performance of those devices. The Meridian®  
14 Filter was developed in furtherance of those efforts. Defendants further admit that a nickel-  
15 titanium alloy named Nitinol is used in the manufacture of the Meridian® Filter. Defendants  
16 deny the remaining allegations contained in Paragraph 59 of Plaintiff's Complaint.

17           60. Defendants deny the Recovery® Filter System, the G2® Filter System,  
18 Eclipse® Filter System, or Meridian® Filter were unreasonably dangerous or defective in any  
19 manner. Defendants admit that there are various well-documented complications that may  
20 occur as a result of the fracture and/or migration of any inferior vena cava filter. Defendants  
21 further admit that it is well-documented that many instances of filter fracture and/or migration  
22 result in no complications whatsoever, but, rather, are completely asymptomatic. By way of  
23 further response, Bard states that there are incidents related to the occurrence of known  
24 complications associated with every manufacturer of inferior vena cava filters. Defendants  
25 deny the remaining allegations of Paragraph 60 of Plaintiff's Complaint.

26           61. Defendants deny the allegations contained in Paragraph 61 of Plaintiff's  
27 Complaint.

1           62. Defendants deny the allegations contained in Paragraph 62 of Plaintiff's  
2 Complaint.

3           63. Defendants deny the allegations contained in Paragraph 63 of Plaintiff's  
4 Complaint.

5           64. Defendants deny the allegations contained in Paragraph 64 of Plaintiff's  
6 Complaint.

7           65. Defendants deny the allegations contained in Paragraph 65 of Plaintiff's  
8 Complaint, including all sub-parts thereof.

9           66. Defendants deny the allegations contained in Paragraph 66 of Plaintiff's  
10 Complaint.

11           67. Defendants deny the allegations contained in Paragraph 67 of Plaintiff's  
12 Complaint.

13           68. Defendants admit that there are various well-documented complications that  
14 may occur as a result of the fracture and/or migration of any inferior vena cava filter.  
15 Defendants further admit that it is well documented than many instances of filter fracture  
16 and/or migration result in no complications whatsoever but, rather, are completely  
17 asymptomatic. By way of further response, Bard states that there are incidents related to the  
18 occurrence of known complications associated with every manufacturer of inferior vena cava  
19 filters. Defendants deny the remaining allegations of Paragraph 68 of Plaintiff's Complaint,  
20 including all sub-parts thereof.

21           69. Defendants deny the allegations contained in Paragraph 69 of Plaintiff's  
22 Complaint.

23           70. Defendants deny the allegations contained in Paragraph 70 of Plaintiff's  
24 Complaint.

25           71. Defendants deny the allegations contained in Paragraph 71 of Plaintiff's  
26 Complaint.

1           72. Defendants deny the allegations contained in Paragraph 72 of Plaintiff's  
2 Complaint, including all sub-parts thereof.

3           73. Defendants deny the allegations contained in Paragraph 73 of Plaintiff's  
4 Complaint.

5           74. In response to the allegations contained in Paragraph 74, Bard admits only that  
6 the regulation cited in Paragraph 74 exists, and that it contains, in part, the language quoted.  
7 To the extent the allegations in Paragraph 74 of Plaintiff's Complaint purport to cast liability  
8 upon Defendants, either directly or indirectly, those allegations are denied.

9           75. In response to the allegations contained in Paragraph 75, Bard admits only that  
10 the regulation cited in Paragraph 75 exists, and that it contains, in part, the language quoted.  
11 To the extent the allegations in Paragraph 75 of Plaintiff's Complaint purport to cast liability  
12 upon Defendants, either directly or indirectly, those allegations are denied.

13           76. In response to the allegations contained in Paragraph 76, Bard admits only that  
14 the regulation cited in Paragraph 76 exists, and that it contains, in part, the language quoted.  
15 To the extent the allegations in Paragraph 76 of Plaintiff's Complaint purport to cast liability  
16 upon Defendants, either directly or indirectly, those allegations are denied.

17           77. Defendants deny the allegations contained in Paragraph 77 of Plaintiff's  
18 Complaint.

19           78. In response to the allegations contained in Paragraph 78, Bard admits only that  
20 the statute cited in Paragraph 78 exists. To the extent the allegations in Paragraph 78 of  
21 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
22 those allegations are denied.

23           79. In response to the allegations contained in Paragraph 79, Bard admits only that  
24 the statute cited in Paragraph 79 exists. To the extent the allegations in Paragraph 79 of  
25 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
26 those allegations are denied.

1           80. In response to the allegations contained in Paragraph 80, Bard admits only that  
2 the statute cited in Paragraph 80 exists. To the extent the allegations in Paragraph 80 of  
3 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
4 those allegations are denied.

5           81. In response to the allegations contained in Paragraph 81, Bard admits only that  
6 the regulation cited in Paragraph 81 exists. To the extent the allegations in Paragraph 81 of  
7 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
8 those allegations are denied.

9           82. In response to the allegations contained in Paragraph 82, Bard admits only that  
10 the regulation cited in Paragraph 82 exists. To the extent the allegations in Paragraph 82 of  
11 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
12 those allegations are denied.

13           83. In response to the allegations contained in Paragraph 83, Bard admits only that  
14 the regulation cited in Paragraph 83 exists. To the extent the allegations in Paragraph 83 of  
15 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
16 those allegations are denied.

17           84. In response to the allegations contained in Paragraph 84, Bard admits only that  
18 the regulation cited in Paragraph 84 exists. To the extent the allegations in Paragraph 84 of  
19 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
20 those allegations are denied.

21           85. In response to the allegations contained in Paragraph 85, Bard admits only that  
22 the regulation cited in Paragraph 85 exists. To the extent the allegations in Paragraph 85 of  
23 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
24 those allegations are denied.

25           86. In response to the allegations contained in Paragraph 86, Bard admits only that  
26 the regulation cited in Paragraph 86 exists. To the extent the allegations in Paragraph 86 of  
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1 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
2 those allegations are denied.

3 87. In response to the allegations contained in Paragraph 87, Bard admits only that  
4 the regulation cited in Paragraph 87 exists. To the extent the allegations in Paragraph 87 of  
5 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
6 those allegations are denied.

7 88. In response to the allegations contained in Paragraph 88, Bard admits only that  
8 the regulation cited in Paragraph 88 exists. To the extent the allegations in Paragraph 88 of  
9 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
10 those allegations are denied.

11 89. In response to the allegations contained in Paragraph 89, Bard admits only that  
12 the regulation cited in Paragraph 89 exists. To the extent the allegations in Paragraph 89 of  
13 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
14 those allegations are denied.

15 90. In response to the allegations contained in Paragraph 90, Bard admits only that  
16 the regulation cited in Paragraph 90 exists. To the extent the allegations in Paragraph 90 of  
17 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
18 those allegations are denied.

19 91. In response to the allegations contained in Paragraph 91, Bard admits only that  
20 the regulation cited in Paragraph 91 exists. To the extent the allegations in Paragraph 91 of  
21 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
22 those allegations are denied.

23 92. In response to the allegations contained in Paragraph 92, Bard admits only that  
24 the regulation cited in Paragraph 92 exists. To the extent the allegations in Paragraph 92 of  
25 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
26 those allegations are denied.

1           93. In response to the allegations contained in Paragraph 93, Bard admits only that  
2 the regulation cited in Paragraph 93 exists. To the extent the allegations in Paragraph 93 of  
3 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
4 those allegations are denied.

5           94. In response to the allegations contained in Paragraph 94, Bard admits only that  
6 the regulation cited in Paragraph 94 exists. To the extent the allegations in Paragraph 94 of  
7 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
8 those allegations are denied.

9           95. In response to the allegations contained in Paragraph 95, Bard admits only that  
10 the regulation cited in Paragraph 95 exists. To the extent the allegations in Paragraph 95 of  
11 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
12 those allegations are denied.

13           96. In response to the allegations contained in Paragraph 96, Bard admits only that  
14 the regulation cited in Paragraph 96 exists. To the extent the allegations in Paragraph 96 of  
15 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
16 those allegations are denied.

17           97. In response to the allegations contained in Paragraph 97, Bard admits only that  
18 the statute cited in Paragraph 97 exists. To the extent the allegations in Paragraph 97 of  
19 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
20 those allegations are denied.

21           98. In response to the allegations contained in Paragraph 98, Bard admits only that  
22 the regulation cited in Paragraph 98 exists. To the extent the allegations in Paragraph 98 of  
23 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
24 those allegations are denied, including all sub-parts thereof.

25           99. In response to the allegations contained in Paragraph 99, Bard admits only that  
26 the regulation cited in Paragraph 99 exists. To the extent the allegations in Paragraph 99 of  
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1 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
2 those allegations are denied.

3 100. In response to the allegations contained in Paragraph 100, Bard admits only that  
4 the regulation cited in Paragraph 100 exists. To the extent the allegations in Paragraph 100 of  
5 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
6 those allegations are denied.

7 101. In response to the allegations contained in Paragraph 101, Bard admits only that  
8 the regulation cited in Paragraph 101 exists. To the extent the allegations in Paragraph 101 of  
9 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
10 those allegations are denied.

11 102. In response to the allegations contained in Paragraph 102, Bard admits only that  
12 the regulation cited in Paragraph 102 exists. To the extent the allegations in Paragraph 102 of  
13 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
14 those allegations are denied.

15 103. In response to the allegations contained in Paragraph 103, Bard admits only that  
16 the regulation cited in Paragraph 103 exists. To the extent the allegations in Paragraph 103 of  
17 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
18 those allegations are denied.

19 104. In response to the allegations contained in Paragraph 104, Bard admits only that  
20 the regulation cited in Paragraph 104 exists. To the extent the allegations in Paragraph 104 of  
21 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
22 those allegations are denied.

23 105. In response to the allegations contained in Paragraph 105, Bard admits only that  
24 the regulation cited in Paragraph 105 exists. To the extent the allegations in Paragraph 105 of  
25 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
26 those allegations are denied.



1           106. In response to the allegations contained in Paragraph 106, Bard admits only that  
2 the regulation cited in Paragraph 106 exists. To the extent the allegations in Paragraph 106 of  
3 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
4 those allegations are denied.

5           107. In response to the allegations contained in Paragraph 107, Bard admits only that  
6 the regulation cited in Paragraph 107 exists. To the extent the allegations in Paragraph 107 of  
7 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
8 those allegations are denied.

9           108. In response to the allegations contained in Paragraph 108, Bard admits only that  
10 the regulation cited in Paragraph 108 exists. To the extent the allegations in Paragraph 108 of  
11 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
12 those allegations are denied.

13           109. In response to the allegations contained in Paragraph 109, Bard admits only that  
14 the regulation cited in Paragraph 109 exists. To the extent the allegations in Paragraph 109 of  
15 Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly,  
16 those allegations are denied, including all sub-parts thereof.

17           110. Defendants admit the Meridian® Filter System was cleared by the United States  
18 Food and Drug Administration pursuant to an application submitted under Section 510(k) of  
19 the Food, Drug and Cosmetic Act in 2010. Defendants deny any remaining allegations  
20 contained in Paragraph 110 of Plaintiff's Complaint.

21           111. Defendants admit the Meridian® Filter System was cleared by the United States  
22 Food and Drug Administration pursuant to an application submitted under Section 510(k) of  
23 the Food, Drug and Cosmetic Act in 2011. Defendants deny any remaining allegations  
24 contained in Paragraph 111 of Plaintiff's Complaint

25           112. Defendants deny the allegations contained in Paragraph 112 of Plaintiff's  
26 Complaint.

1 113. Defendants deny the allegations contained in Paragraph 113 of Plaintiff's  
2 Complaint.

3 114. Defendants deny the allegations contained in Paragraph 114 of Plaintiff's  
4 Complaint.

5 115. Defendants deny the allegations contained in Paragraph 115 of Plaintiff's  
6 Complaint.

7 116. Defendants deny the allegations contained in Paragraph 116 of Plaintiff's  
8 Complaint.

9 117. Defendants are without knowledge or information sufficient to form a belief as  
10 to the truth of the allegations contained in Paragraph 117 of Plaintiff's Complaint and, on that  
11 basis, deny them.

12 118. Defendants are without knowledge or information sufficient to form a belief as  
13 to the truth of the allegations regarding the trade name of any inferior vena cava filter  
14 implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining  
15 allegations of Paragraph 118 of Plaintiff's Complaint.

16 119. Defendants deny the allegations contained in Paragraph 119 of Plaintiff's  
17 Complaint.

18 120. Defendants deny the allegations contained in Paragraph 120 of Plaintiff's  
19 Complaint.

20 121. Defendants deny the allegations contained in Paragraph 121 of Plaintiff's  
21 Complaint.

22 122. Defendants deny the allegations contained in Paragraph 122 of Plaintiff's  
23 Complaint.

24 123. Defendants deny the allegations contained in Paragraph 123 of Plaintiff's  
25 Complaint.

26 124. Defendants deny the allegations contained in Paragraph 124 of Plaintiff's  
27 Complaint.

125. Defendants deny the allegations contained in Paragraph 125 of Plaintiff's Complaint.

126. Defendants deny the allegations contained in Paragraph 126 of Plaintiff's Complaint.

### **FIRST CAUSE OF ACTION**

#### **NEGLIGENCE**

127. Defendants incorporate by reference their responses to Paragraphs 1-126 of Plaintiff's Complaint as if fully set forth herein.

128. Defendants deny the allegations of Paragraph 128 of Plaintiff's Complaint as stated. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Meridian® were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Meridian®. Defendants deny any remaining allegations contained in Paragraph 128 of Plaintiff's Complaint.

129. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining allegations of Paragraph 129 of Plaintiff's Complaint.

130. The allegations contained in Paragraph 130 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 130 of Plaintiff's Complaint.

131. Defendants deny the allegations contained in Paragraph 131 of Plaintiff's Complaint.

132. Defendants deny the allegations contained in Paragraph 132 of Plaintiff's Complaint, including all sub-parts thereof.

1 133. Defendants deny the allegations contained in Paragraph 133 of Plaintiff's  
2 Complaint.

3 134. Defendants deny the allegations contained in Paragraph 134 of Plaintiff's  
4 Complaint.

5 135. Defendants deny the allegations contained in Paragraph 135 of Plaintiff's  
6 Complaint, including all sub-parts thereof.

7 136. Defendants deny the allegations contained in Paragraph 136 of Plaintiff's  
8 Complaint.

9 137. Defendants deny the allegations contained in Paragraph 137 of Plaintiff's  
10 Complaint.

11 **SECOND CAUSE OF ACTION**

12 **STRICT PRODUCTS LIABILITY – FAILURE TO WARN**

13 138. Defendants incorporate by reference their responses to Paragraphs 1-137 of  
14 Plaintiff's Complaint as if fully set forth herein.

15 139. Defendants are without knowledge or information sufficient to form a belief as  
16 to the truth of the allegations regarding the trade name of any inferior vena cava filter  
17 implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants  
18 admit that Bard owns a facility where vena cava filters are manufactured and that filters under  
19 the trademark Meridian® were manufactured at that facility. Defendants further admit that  
20 BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed,  
21 sold, marketed, and distributed filters under the trademark Meridian®. Defendants deny any  
22 remaining allegations contained in Paragraph 139 of Plaintiff's Complaint.

23 140. Defendants deny the allegations contained in Paragraph 140 of Plaintiff's  
24 Complaint.

25 141. Defendants deny the allegations contained in Paragraph 141 of Plaintiff's  
26 Complaint.

1 142. Defendants deny the allegations contained in Paragraph 142 of Plaintiff's  
2 Complaint.

3 143. Defendants deny the allegations contained in Paragraph 143 of Plaintiff's  
4 Complaint.

5 144. Defendants deny the allegations contained in Paragraph 144 of Plaintiff's  
6 Complaint.

7 145. Defendants deny the allegations contained in Paragraph 145 of Plaintiff's  
8 Complaint.

9 146. Defendants deny the allegations contained in Paragraph 146 of Plaintiff's  
10 Complaint.

11 147. Defendants deny the allegations contained in Paragraph 147 of Plaintiff's  
12 Complaint.

13 148. Defendants deny the allegations contained in Paragraph 148 of Plaintiff's  
14 Complaint.

15 149. Defendants deny the allegations contained in Paragraph 149 of Plaintiff's  
16 Complaint.

17 150. Defendants deny the allegations contained in Paragraph 150 of Plaintiff's  
18 Complaint.

19 151. Defendants deny the allegations contained in Paragraph 151 of Plaintiff's  
20 Complaint.

21 152. Defendants deny the allegations contained in Paragraph 152 of Plaintiff's  
22 Complaint.

23 **THIRD CAUSE OF ACTION**

24 **STRICT PRODUCTS LIABILITY – DESIGN DEFECTS**

25 153. Defendants incorporate by reference their responses to Paragraphs 1-152 of  
26 Plaintiff's Complaint as if fully set forth herein.

154. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Meridian® were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Meridian®. Defendants deny any remaining allegations contained in Paragraph 154 of Plaintiff's Complaint.

155. Defendants deny the allegations contained in Paragraph 155 of Plaintiff's Complaint.

156. Defendants deny the allegations contained in Paragraph 156 of Plaintiff's Complaint.

157. Defendants deny the allegations contained in Paragraph 157 of Plaintiff's Complaint.

158. Defendants deny the allegations contained in Paragraph 158 of Plaintiff's Complaint.

159. Defendants deny the allegations contained in Paragraph 159 of Plaintiff's Complaint.

160. Defendants deny the allegations contained in Paragraph 160 of Plaintiff's Complaint.

#### **FOURTH CAUSE OF ACTION**

##### **STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

161. Defendants incorporate by reference their responses to Paragraphs 1-160 of Plaintiff's Complaint as if fully set forth herein.

162. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants

1 admit that Bard owns a facility where vena cava filters are manufactured and that filters under  
 2 the trademark Meridian® were manufactured at that facility. Defendants further admit that  
 3 BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed,  
 4 sold, marketed, and distributed filters under the trademark Meridian®. Defendants deny any  
 5 remaining allegations contained in Paragraph 162 of Plaintiff's Complaint.

6 163. Defendants deny the allegations contained in Paragraph 163 of Plaintiff's  
 7 Complaint.

8 164. Defendants deny the allegations contained in Paragraph 164 of Plaintiff's  
 9 Complaint.

10 165. Defendants deny the allegations contained in Paragraph 165 of Plaintiff's  
 11 Complaint.

12 166. Defendants deny the allegations contained in Paragraph 166 of Plaintiff's  
 13 Complaint.

#### 14 **FIFTH CAUSE OF ACTION**

#### 15 **BREACH OF EXPRESS WARRANTY**

16 167. Defendants incorporate by reference their responses to Paragraphs 1-166 of  
 17 Plaintiff's Complaint as if fully set forth herein.

18 168. Defendants deny the allegations contained in Paragraph 168 of Plaintiff's  
 19 Complaint.

20 169. Defendants deny the allegations contained in Paragraph 169 of Plaintiff's  
 21 Complaint.

22 170. Defendants deny the allegations contained in Paragraph 170 of Plaintiff's  
 23 Complaint.

24 171. Defendants deny the allegations contained in Paragraph 171 of Plaintiff's  
 25 Complaint.

26 172. Defendants deny the allegations contained in Paragraph 172 of Plaintiff's  
 27 Complaint.

1 173. Defendants deny the allegations contained in Paragraph 173 of Plaintiff's  
2 Complaint.

3 174. Defendants deny the allegations contained in Paragraph 174 of Plaintiff's  
4 Complaint.

5 175. Defendants deny the allegations contained in Paragraph 175 of Plaintiff's  
6 Complaint.

7 **SIXTH CAUSE OF ACTION**

8 **BREACH OF IMPLIED WARRANTY**

9 176. Defendants incorporate by reference their responses to Paragraphs 1-175 of  
10 Plaintiff's Complaint as if fully set forth herein.

11 177. Defendants deny the allegations contained in Paragraph 177 of Plaintiff's  
12 Complaint.

13 178. Defendants deny the allegations contained in Paragraph 178 of Plaintiff's  
14 Complaint.

15 179. Defendants deny the allegations contained in Paragraph 179 of Plaintiff's  
16 Complaint.

17 180. Defendants deny the allegations contained in Paragraph 180 of Plaintiff's  
18 Complaint.

19 181. Defendants deny the allegations contained in Paragraph 181 of Plaintiff's  
20 Complaint, including all sub-parts thereof.

21 182. Defendants deny the allegations contained in Paragraph 182 of Plaintiff's  
22 Complaint.

23 183. Defendants deny the allegations contained in Paragraph 183 of Plaintiff's  
24 Complaint.

25 184. Defendants deny the allegations contained in Paragraph 184 of Plaintiff's  
26 Complaint.



1 185. Defendants deny the allegations contained in Paragraph 185 of Plaintiff's  
2 Complaint.

3 **SEVENTH CAUSE OF ACTION**

4 **FRAUDULENT MISREPRESENTATION**

5 186. Defendants incorporate by reference their responses to Paragraphs 1-185 of  
6 Plaintiff's Complaint as if fully set forth herein.

7 187. The allegations contained in Paragraph 187 are legal conclusions of law, and no  
8 answer is required. To the extent a response is required, Defendants deny the allegations.  
9 Defendants any remaining allegations contained in Paragraph 187 of Plaintiff's Complaint.

10 188. Defendants deny the allegations contained in Paragraph 188 of Plaintiff's  
11 Complaint.

12 189. Defendants deny the allegations contained in Paragraph 189 of Plaintiff's  
13 Complaint.

14 190. Defendants deny the allegations contained in Paragraph 190 of Plaintiff's  
15 Complaint.

16 191. Defendants deny the allegations contained in Paragraph 191 of Plaintiff's  
17 Complaint.

18 192. Defendants deny the allegations contained in Paragraph 192 of Plaintiff's  
19 Complaint.

20 193. Defendants deny the allegations contained in Paragraph 193 of Plaintiff's  
21 Complaint.

22 194. Defendants deny the allegations contained in Paragraph 194 of Plaintiff's  
23 Complaint.

24 195. Defendants deny the allegations contained in Paragraph 195 of Plaintiff's  
25 Complaint.

**EIGHTH CAUSE OF ACTION**

**NEGLIGENT MISREPRESENTATION**

196. Defendants incorporate by reference their responses to Paragraphs 1-195 of Plaintiff's Complaint as if fully set forth herein.

197. Defendants deny the allegations contained in Paragraph 197 of Plaintiff's Complaint, including all sub-parts thereof.

198. Defendants deny the allegations contained in Paragraph 198 of Plaintiff's Complaint.

199. Defendants deny the allegations contained in Paragraph 199 of Plaintiff's Complaint.

200. Defendants deny the allegations contained in Paragraph 200 of Plaintiff's Complaint.

201. Defendants deny the allegations contained in Paragraph 201 of Plaintiff's Complaint.

202. Defendants deny the allegations contained in Paragraph 202 of Plaintiff's Complaint.

203. Defendants deny the allegations contained in Paragraph 203 of Plaintiff's Complaint.

204. Defendants deny the allegations contained in Paragraph 204 of Plaintiff's Complaint.

205. Defendants deny the allegations contained in Paragraph 205 of Plaintiff's Complaint.

206. Defendants deny the allegations contained in Paragraph 206 of Plaintiff's Complaint.

**PUNITIVE DAMAGES ALLEGATIONS**

207. Defendants incorporate by reference their responses to Paragraphs 1-206 of Plaintiff's Complaint as if fully set forth herein.

208. Defendants deny the allegations contained in Paragraph 208 of Plaintiff's Complaint.

209. Defendants deny the allegations contained in Paragraph 209 of Plaintiff's Complaint.

210. Defendants deny the allegations contained in Paragraph 210 of Plaintiff's Complaint.

211. Defendants deny the allegations contained in Paragraph 211 of Plaintiff's Complaint.

212. Defendants deny the allegations contained in Paragraph 212 of Plaintiff's Complaint.

213. Defendants deny the allegations contained in Paragraph 213 of Plaintiff's Complaint, including all sub-parts thereof.

214. Defendants deny the allegations contained in Paragraph 214 of Plaintiff's Complaint.

215. Defendants deny the allegations contained in Paragraph 215 of Plaintiff's Complaint.

#### **PRAYER FOR DAMAGES**

Furthermore, responding to the unnumbered Paragraph, including sub-parts, following the heading "PRAYER FOR DAMAGES" and beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph and all sub-parts thereof.

Defendants further deny each and every allegation not specifically admitted herein.

Defendants allege as affirmative defenses the following:

1. Plaintiff's Complaint filed herein fails to state a claim or claims upon which relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

2. The sole proximate cause of Plaintiff's damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions Defendants were and are in no way liable.

1           3.     Plaintiff's claims are barred, in whole or in part, by the applicable statutes of  
2 limitations and/or statute of repose.

3           4.     If Plaintiff has been damaged, which Defendants deny, any recovery by  
4 Plaintiff is barred to the extent Plaintiff voluntarily exposed herself to a known risk and/or  
5 failed to mitigate their alleged damages. To the extent Plaintiff has failed to mitigate her  
6 alleged damages, any recovery shall not include alleged damages that could have been  
7 avoided by reasonable care and diligence.

8           5.     If Plaintiff has been damaged, which Defendants deny, such damages were  
9 caused by the negligence or fault of Plaintiff.

10          6.     If Plaintiff has been damaged, which Defendants deny, such damages were  
11 caused by the negligence or fault of persons and/or entities for whose conduct Defendants are  
12 not legally responsible.

13          7.     The conduct of Defendants and the subject product at all times conformed with  
14 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*, and other pertinent  
15 federal statutes and regulations. Accordingly, Plaintiff's claims are barred, in whole or in  
16 part, under the doctrine of federal preemption, and granting the relief requested would  
17 impermissibly infringe upon and conflict with federal laws, regulations, and policies in  
18 violation of the Supremacy Clause of the United States Constitution.

19          8.     If Plaintiff has been damaged, which Defendants deny, such damages were  
20 caused by unforeseeable, independent, intervening, and/or superseding events for which  
21 Defendants are not legally responsible.

22          9.     There was no defect in the product at issue with the result that Plaintiff is not  
23 entitled to recover against Defendants in this cause.

24          10.    If there were any defect in the products – and Defendants deny that there were  
25 any defects – nevertheless, there was no causal connection between any alleged defect and  
26 the product on the one hand and any damage to Plaintiff on the other with the result that  
27 Plaintiff is not entitled to recover against Defendants in this cause.  
28

1           11. Plaintiff's injuries, losses or damages, if any, were caused by or contributed to  
2 by other persons or entities that are severally liable for all or part of Plaintiff's alleged  
3 injuries, losses or damages. If Defendants are held liable to Plaintiff, which liability is  
4 specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification,  
5 either in whole or in part, from all persons or entities whose negligence or fault proximately  
6 caused or contributed to cause Plaintiff's alleged damages.

7           12. Plaintiff's claims are barred to the extent that the injuries alleged in the  
8 Complaint were caused by the abuse, misuse, abnormal use, or use of the product at issue in a  
9 manner not intended by Defendants and over which Defendants had no control.

10           13. Plaintiff's claims are barred to the extent that the injuries alleged in the  
11 Complaint were caused by a substantial change in the product after leaving the possession,  
12 custody, and control of Defendants.

13           14. Plaintiff's breach of warranty claims are barred because: (1) Defendants did not  
14 make any warranties, express or implied, to Plaintiff; (2) there was a lack of privity between  
15 Defendants and Plaintiff; and (3) notice of an alleged breach was not given to the seller or  
16 Defendants.

17           15. Plaintiff's claims for breach of implied warranty must fail because the product  
18 was not used for its ordinary purpose.

19           16. Defendants neither had nor breached any alleged duty to warn with respect to  
20 the product, with the result that Plaintiff is not entitled to recover in this cause.

21           17. Plaintiff's claims are barred by Defendants' dissemination of legally adequate  
22 warnings and instructions to learned intermediaries.

23           18. At all relevant times, herein, Plaintiff's physicians were in the position of  
24 sophisticated purchasers, fully knowledgeable and informed with respect to the risks and  
25 benefits of the subject product.

26           19. If Plaintiff has been damaged, which Defendants deny, the actions of persons or  
27 entities for whose conduct Defendants are not legally responsible and the independent  
28

1 knowledge of these persons or entities of the risks inherent in the use of the product and other  
2 independent causes, constitute an intervening and superseding cause of Plaintiff's alleged  
3 damages.

4 20. To the extent that injuries and damages sustained by Plaintiff, as alleged in  
5 Plaintiff's Complaint, were caused directly, solely, and proximately by sensitivities, medical  
6 conditions, and idiosyncrasies peculiar to Plaintiff not found in the general public, they were  
7 unknown, unknowable, or not reasonably foreseeable to Defendants.

8 21. Defendants believe, and upon that ground allege, that Plaintiff were advised of  
9 the risks associated with the matters alleged in Plaintiff's Complaint and knowingly and  
10 voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed  
11 consent, release, waiver, or comparative fault, this conduct bars in whole or in part the  
12 damages that Plaintiff seek to recover herein.

13 22. At all relevant times during which the device at issue was designed, developed,  
14 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended  
15 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,  
16 information, and instructions, all pursuant to generally recognized prevailing industry  
17 standards and state-of-the-art in existence at the time.

18 23. Plaintiff's claims are barred because Plaintiff suffered no injury or damages as a  
19 result of the alleged conduct and do not have any right, standing, or competency to maintain  
20 claims for damages or other relief.

21 24. Plaintiff's claims are barred, in whole or in part, by the doctrines of waiver,  
22 estoppel, and/or laches.

23 25. If Plaintiff suffered any damages or injuries, which are denied, Defendants state  
24 that Plaintiff's recovery is barred, in whole or in part, or subject to reduction, under the  
25 doctrines of contributory and/or comparative negligence.

26 26. In the further alternative, and only in the event that it is determined that  
27 Plaintiff is entitled to recover against Defendants, recovery should be reduced in proportion to  
28

1 the degree or percentage of negligence, fault or exposure to products attributable to Plaintiff,  
2 any other defendants, third-party defendants, or other persons, including any party immune  
3 because bankruptcy renders them immune from further litigation, as well as any party, co-  
4 defendant, or non-parties with whom Plaintiff has settled or may settle in the future.

5 27. Should Defendants be held liable to Plaintiff, which liability is specifically  
6 denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiff  
7 from all collateral sources.

8 28. Plaintiff's claims may be barred, in whole or in part, from seeking recovery  
9 against Defendants pursuant to the doctrines of res judicata, collateral estoppel, release of  
10 claims, and the prohibition on double recovery for the same injury.

11 29. The injuries and damages allegedly sustained by Plaintiff may be due to the  
12 operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiff  
13 over which Defendants had no control.

14 30. The conduct of Defendants and all activities with respect to the subject product  
15 have been and are under the supervision of the Federal Food and Drug Administration  
16 ("FDA"). Accordingly, this action, including any claims for monetary and/or injunctive relief,  
17 is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

18 31. Defendants assert any and all defenses, claims, credits, offsets, or remedies  
19 provided by the Restatements (Second and Third) of Torts and reserve the right to amend  
20 their Answer to file such further pleadings as are necessary to preserve and assert such  
21 defenses, claims, credits, offsets, or remedies.

22 32. The device at issue complied with any applicable product safety statute or  
23 administrative regulation, and therefore Plaintiff's defective design and warnings-based  
24 claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq.* and  
25 comments thereto.

26 33. Plaintiff cannot show that any reasonable alternative design would have  
27 rendered the G2® Filter inferior vena cava filter device as alleged in Plaintiff's Complaint to  
28

1 be safer overall under the Restatement (Third) of Product Liability § 2, cmt. f, nor could  
2 Defendants have known of any alternative design that may be identified by Plaintiff.

3 34. The device at issue was not sold in a defective condition unreasonably  
4 dangerous to the user or consumer, and therefore Plaintiff's claims are barred under the  
5 Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and  
6 comparable provisions of the Restatement (Third) of Torts (Products Liability).

7 35. At all relevant times during which the device at issue was designed, developed,  
8 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended  
9 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,  
10 information, and instructions, all pursuant to generally recognized prevailing industry  
11 standards and state-of-the-art in existence at the time.

12 36. Defendants specifically plead all affirmative defenses under the Uniform  
13 Commercial Code ("UCC") now existing or which may arise in the future, including those  
14 defenses provided by UCC §§ 2-607 and 2-709.

15 37. Plaintiff's alleged damages, if any, should be apportioned among all parties at  
16 fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors  
17 Act.

18 38. No act or omission of Defendants was malicious, willful, wanton, reckless, or  
19 grossly negligent, and, therefore, any award of punitive damages is barred.

20 39. To the extent the claims asserted in Plaintiff's Complaint are based on a theory  
21 providing for liability without proof of defect and proof of causation, the claims violate  
22 Defendants' rights under the Constitution of the United States and analogous provisions of  
23 the Virginia Constitution.

24 40. Regarding Plaintiff's demand for punitive damages, Defendants specifically  
25 incorporate by reference any and all standards of limitations regarding the determination  
26 and/or enforceability of punitive damages awards that arose in the decisions of *BMW of*  
27 *No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool*  
28



1 *Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct.  
 2 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S.  
 3 June 25, 2008) and their progeny as well as other similar cases under both federal and state  
 4 law.

5 41. Plaintiff's claims for punitive or exemplary damages violate, and are therefore  
 6 barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of  
 7 the United States of America, and similar provisions of the Virginia Constitution, on grounds  
 8 including the following:

- 9 (a) it is a violation of the Due Process and Equal Protection Clauses of the  
 10 Fourteenth Amendment of the United States Constitution to impose punitive  
 11 damages, which are penal in nature, against a civil defendant upon the plaintiff  
 12 satisfying a burden of proof which is less than the "beyond a reasonable doubt"  
 13 burden of proof required in criminal cases;
- 14 (b) the procedures pursuant to which punitive damages are awarded may result in  
 15 the award of joint and several judgments against multiple defendants for  
 16 different alleged acts of wrongdoing, which infringes upon the Due Process and  
 17 Equal Protection Clauses of the Fourteenth Amendment of the United States  
 18 Constitution;
- 19 (c) the procedures to which punitive damages are awarded fail to provide a  
 20 reasonable limit on the amount of the award against Defendants, which thereby  
 21 violates the Due Process Clause of the Fourteenth Amendment of the United  
 22 States Constitution;
- 23 (d) the procedures pursuant to which punitive damages are awarded fail to provide  
 24 specific standards for the amount of the award of punitive damages which  
 25 thereby violates the Due Process Clause of the Fourteenth Amendment of the  
 26 United States Constitution;

1 (e) the procedures pursuant to which punitive damages are awarded result in the  
2 imposition of different penalties for the same or similar acts, and thus violate  
3 the Equal Protection Clause of the Fourteenth Amendment of the United States  
4 Constitution;

5 (f) the procedures pursuant to which punitive damages are awarded permit the  
6 imposition of punitive damages in excess of the maximum criminal fine for the  
7 same or similar conduct, which thereby infringes upon the Due Process Clause  
8 of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the  
9 Fourteenth Amendment of the United States Constitution;

10 (g) the procedures pursuant to which punitive damages are awarded permit the  
11 imposition of excessive fines in violation of the Eighth Amendment of the  
12 United States Constitution;

13 (h) the award of punitive damages to the plaintiff in this action would constitute a  
14 deprivation of property without due process of law; and

15 (i) the procedures pursuant to which punitive damages are awarded permit the  
16 imposition of an excessive fine and penalty.

17 42. Defendants expressly reserve the right to raise as an affirmative defense that  
18 Plaintiff has failed to join all parties necessary for a just adjudication of this action, should  
19 discovery reveal the existence of facts to support such defense.

20 43. The design complained of in Plaintiffs' Complaint, the alleged defects of the  
21 product, and/or any alternative design claimed by Plaintiffs were not known and, in light of  
22 the existing, reasonably-available scientific and technological knowledge, could not have  
23 been known at the time the product at issue was designed, manufactured, and sold. Any  
24 alleged alternative design was not scientifically or technologically feasible or economically  
25 practical.

44. To the extent the Complaint alleges misrepresentation and fraud, these allegations do not comply with the requisite of particularity under applicable procedural rules and/or law.

45. This case may be subject to dismissal or transfer under the doctrine of forum non conveniens.

46. Defendants reserve the right to raise such other affirmative defenses as may be available or apparent during discovery or as may be raised or asserted by other defendants in this case. Defendants have not knowingly or intentionally waived any applicable affirmative defense. If it appears that any affirmative defense is or may be applicable after Defendants have had the opportunity to conduct reasonable discovery in this matter, Defendants will assert such affirmative defense in accordance with the Federal Rules of Civil Procedure.

#### **REQUEST FOR JURY TRIAL**

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury on all issues appropriate for jury determination.

**WHEREFORE**, Defendants aver that Plaintiff is not entitled to the relief demanded in the Complaint, and these Defendants, having fully answered, pray that this action against them be dismissed and that they be awarded their costs in defending this action and that they be granted such other and further relief as the Court deems just and appropriate.

This 23rd day of October 2015.

s/Richard B. North, Jr.  
 Richard B. North, Jr.  
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**Attorney for Defendants C. R. Bard, Inc. and  
Bard Peripheral Vascular, Inc.**

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on October 23, 2015, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

s/Richard B. North, Jr.  
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